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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,589	Applicant(s) CARTER ET AL.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the applicant's amendment received 12 May 2010. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 1-23 and 33-36 remain cancelled. New claims 40-42 have been added.

Response to Arguments

Applicant's arguments filed 12 May 2010 have been fully considered but they are not persuasive.

The applicant first argues that Shaknovich fails to disclose or suggest advancing the first introducer independent of the second introducer and advancing the second introducer entirely external to the first introducer. However, it is the examiner's position that Shaknovich does disclose advancing a first introducer (1a) independent of a second introducer (1b) and advancing a second introducer entirely external to the first introducer (for example, Figure 9 shows the introducers as two separate and independent introducers that are entirely external of one another) as required by the claims (see rejection).

The applicant then argues that Hilaire's method teaches away from Shaknovich's method. However, Hilaire's method is not being modified to require advancing the introducers independent of each other or require advancing a wire guide entirely external to and independent of the first stent as argued by the applicant. Hilaire provides the teaching that the step of staggering two introducers in an initial adjacent configuration is well known in the art in order to reduce the profile of the system (for

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example, see paragraphs 54 and 110). Since Shaknovich does not teach away from initially staggering the introducers to advance the system to the deployment site, such a modification would have been obvious to one having ordinary skill in the art at the time of the invention in order to reduce the delivery profile of the system, thus reducing the risk of injury to body lumens during advancement (see rejection).

The applicant finally argues that Shaknovich is directed to vascular applications and there is no reason for providing an endoscope described in Colgan for direct visualization of stent placement in the vasculature, both because of the size of vasculature and the ability of skilled artisans to place stents in the vasculature without direct visualization. However, Shaknovich suggests the invention may be used for “bifurcating vessels or similar conduits, such as, but not limited to, tubular branched organs or spaces such as a proximal ureter, the junction of the common hepatic duct and the cystic duct to form the common bile duct, or a branched bronchus or trachea” (for example, see column 10, lines 16-24). Therefore, the applicant’s argument is rendered moot.

Finally, it is the examiner’s position that that Shaknovich as modified by Hilaire and Colgan above (and described in the rejection below) provides for the step of placing two introducers, each having a stent mounted thereto, in a staggered, adjacent configuration in a working channel of an endoscope as required by the claims.

With respect to the applicant’s argument that Shaknovich fails to teach or suggest placing and/or advancing the introducers and/or stents in “a biliary system” as now required by amended claim 30 and new claims 40 and 42, it is the examiner’s

position that Shaknovich teaches stenting the junction that forms the bile duct is well known in the art and thus such a step would have been obvious to one having ordinary skill in the art at the time of the invention in order to stent the junction that forms the bile duct (see new rejection below necessitated by the applicant's amendment).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-32 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (U.S. Patent No. 5,669,924), Hilaire et al. (U.S. Publication No. 2005/0085845 A1), and Colgan et al. (U.S. Publication No. 2003/0040789 A1).

Shaknovich discloses a method of placing first and second stents into a bifurcation using a stent delivery device (for example, see Figure 9) comprising the

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steps of providing a first introducer (1a) having a first distal portion (balloon of 1a) with a first distal outer diameter and a first stent (6a) and a first proximal portion (shaft of 1a) having a first proximal outer diameter that is less than the first distal outer diameter, providing a second introducer (1b) having a second distal portion (balloon of 1b) with a second distal outer diameter and a second stent (6b) and a second proximal portion (shaft of 1b) having a second proximal outer diameter that is less than the second distal diameter, placing a first (5a) and second (5b) wire guide in an adjacent configuration external to and independent of the opposite stents and introducers into a main lumen and first and second branch lumens, subsequently independently advancing the first and second introducers over the first and second wire guides such that the first introducer is positioned within the main lumen and first branch lumen and the second introducer is positioned within the main lumen and the second branch lumen (in that the main lumen branches to either the left or straight, thus the straight portion at the branching section is considered a first branch and the left portion is considered a second branch as claimed; for example, see Figure 9 and column 8, lines 17-22), simultaneously or sequentially (for example, see column 4, lines 15-20) deploying the first and second stents such that at least at least a portion of the first stent is in a side-by-side configuration with at least a portion of the proximal portion of the second stent within the main lumen, and inherently withdrawing the first and second introducers after completing the procedure. Shakhovich teaches it is well known in the art to stent the junction that forms the bile duct (for example, see column 10, lines 16-24) and thus to place and/or advance the introducers and/or stents into the "biliary system" would have

been obvious to one having ordinary skill in the art at the time of the invention in order to repair the junction that forms the bile duct.

Shaknovich fails to disclose placing and advancing the first and second introducers in a staggered adjacent configuration, wherein the first proximal portion is adjacent to the second distal portion such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter.

Hilaire discloses a method for placing stents in a bifurcation. Hilaire teaches placing and advancing the introducers in a staggered relationship such that the first proximal portion is adjacent to the second distal portion and such that an overall diameter of the first and second introducers is less than the sum of the first distal outer diameter and the second distal outer diameter (for example, see Figure 5) in order to provide a delivery system having a low profile (for example, see paragraph 54). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place and advance Shaknovich's introducers as taught by Hilaire. Doing so would provide the advantage described above and thus reduce the risk of injury to body lumens during advancement.

Shaknovich as modified by Hilaire fails to disclose the step of placing the staggered, adjacent, introducers (for example, see Figure 2) in a working channel of an endoscope. Colgan discloses a method of deploying a stent (see entire document). Colgan teaches the step of placing an introducer retaining a stent in a working channel of an endoscope (70; for example, see paragraphs 87 and 91). It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to place the introducers of Shaknovich as modified by Hilaire in a working channel of an endoscope as taught by Colgan. Doing so would enable the operator to locate stent placement through direct vision (for example, see paragraph 87).

With further respect to claim 41, Shaknovich teaches self-expanding stents are also well known in the art (for example, see column 2, lines 10-13) and thus, utilizing self-expanding stents would have been obvious to one having ordinary skill in the art at the time of the invention in order to assist in the initial expansion of the stents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose e-mail is Melanie.tyson@uspto.gov and telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 10-8 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
July 6, 2010